Medtronic

Software License Agreement

May 2020, updated May 2022

Background

The medical and healthcare communities in the United States and across the world currently are responding to a medical emergency involving spread of the Novel Coronavirus Disease ("COVID-19"). On January 30, 2020, the World Health Organization ("WHO") declared the outbreak of COVID-19 a Public Health Emergency of International Concern ("PHEIC"), and, on March 11, 2020, the WHO Director General declared COVID-19 a pandemic. On March 13, 2020, President Donald J. Trump declared a National Emergency in the United States due to the COVID-19 outbreak.

As the U.S. Food and Drug Administration ("FDA") stated in its March 2020 ventilator guidance ("FDA Guidance"), it is necessary to maintain an adequate supply of mechanical ventilators "to support patients who develop respiratory compromise from COVID-19." Consistent with the FDA Guidance, and in accordance with the public health and medical response of governmental agencies around the world, Medtronic is releasing the software package described below (the "Software Package") for remote in-hospital adjustment of the Puritan Bennett PB980 ventilator to help doctors and patients dealing with COVID-19 (the "Purpose").

Acknowledgment

COVIDIEN LP ("MEDTRONIC") IS MAKING THE SOFTWARE PACKAGE AVAILABLE TO YOU, A HEALTHCARE FACILITY ("INSTITUTION") THAT HAS PREVIOUSLY PURCHASED ONE OR MORE PURITAN BENNETT 980 VENTILATORS (THE "980 VENTILATOR") FROM MEDTRONIC. BY ACCEPTING THIS SOFTWARE LICENSE AGREEMENT (THE "TERMS") AND DOWNLOADING THE SOFTWARE PACKAGE, INSTITUTION AGREES TO THESE TERMS AND AGREES THAT THESE TERMS GOVERN INSTITUTION'S USE OF THE SOFTWARE PACKAGE. THE INDIVIDUAL DOWNLOADING THE SOFTWARE PACKAGE IS AUTHORIZED BY INSTITUTION TO AGREE TO THESE TERMS AND DOWNLOAD THE SOFTWARE PACKAGE ON BEHALF OF INSTITUTION.

Institution represents that it is a healthcare facility in the United States with personnel who possess the appropriate clinical and technical expertise to use the Software Package in a clinical setting, and Institution has expressed a willingness to do so to help doctors and patients dealing with COVID-19.

To the extent that any inconsistent terms are presented to Institution in connection with the download or installation of the Software Package, these Terms govern.

Software Package

The Software Package includes the following, in object code form only: (i) the Omnitool software ("Omnitool"); (ii) the Installation & Reference Guide and other associated videos, instructions, and documentation ("Documentation"); and, if 980 Ventilator updates are performed by Institution, (iii) the Enhanced Service Software ("ESS") and (iv) the OASIS agent device management software ("Agent").

The Software Package is specifically intended to provide the capability for remote adjustment of settings of the 980 Ventilator to reduce exposure of healthcare providers to COVID-19, as contemplated in the FDA Guidance ("Remote Access Feature").

The ESS is part of a Medtronic service designed to update the 980 Ventilators, and to communicate with the Medtronic servers. As part of this process, product log data will be transmitted to Medtronic and stored by Medtronic for support purposes. CUSTOMER AUTHORIZES THE TRANSMISSION OF THE PRODUCT LOG DATA, AND USE OF THE SOFTWARE AS DESCRIBED.

Regulatory

The Remote Access Feature has not been evaluated or cleared by the FDA. The Remote Access Feature is released in accordance with US FDA Enforcement Policy for Ventilators and Accessories and other Respiratory Devices during the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (March 2020).

Software License

License. Subject to and conditioned on Institution's compliance with these Terms, Medtronic hereby grants to Institution a non-exclusive, non-transferable, fully paid-up, royalty free license (without any right to sublicense) to download, install, and use the Software Package in the United States during the Term for the Purpose. Institution may make copies of the Omnitool up to the number of Institution's 980 Ventilators.

Limitations. Institution may not transfer, assign, sublicense, reproduce, modify, distribute, reverse engineer, decompile, disassemble, translate or attempt to discover the source code of the Software Package. The ESS and Agent facilitate authentication of Institution as an authorized user of 980 Ventilators. In connection with such authentication, Medtronic may provide Institution with usernames and passwords. Institution may not share any usernames or passwords with any other entity.

Limited Term. These Terms are effective from the time Institution receives the Software Package until the earlier of: (a) One hundred and eighty (180) days following the expiration or other termination or revocation of the declaration that circumstances exist justifying the emergency use of this feature under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), i.e., one hundred and eighty (180) days following the expiration (through non-renewal) of the Determination that a Public Health Emergency exists as originally declared by the Secretary of Health and Human Services effective January 31, 2020, and thereafter extended in ninety day increments until such expiration.; or (b) May 31, 2023 (the "Term"). Depending on future circumstances, the Term may be extended. At the end of the Term: (i) Institution must un-install and remove the Software Package from Institution's hardware, including deleting and un-installing all copies of the Omnitool, the ESS, and the Agent; (ii) Institution must discontinue all use of the Software Package and Remote Access Feature; (iii) the license granted herein will expire; and (iv) upon request by Medtronic, Institution will certify that the foregoing is complete and/or will permit Medtronic to access Institution's 980 Ventilators to facilitate or confirm accomplishment of item (i) in this paragraph.

Ownership. The Software Package remains the property of Medtronic. Institution does not have any ownership rights or exclusivity to the Software Package. All rights not expressly granted to Institution are reserved by Medtronic. The only rights that Institution has with respect to the Software Package are those that are expressly granted in these Terms; no other rights are granted to Institution, whether implied, by estoppel or otherwise.

Software Installation

This section is applicable if 980 Ventilator updates are performed by Institution. Installing the Software Package is a multi-step process that requires removing the 980 Ventilator from patient use, entering service mode, installing updates, and performing EST (extended self-test), SST (short self-test), and calibrations before returning the 980 Ventilator to patient use. **Due to current high demand on our field service teams to support ventilator maintenance and installations, Medtronic may not be able to provide someone on-site to troubleshoot any technical issues. If Institution is not able to complete all steps of the installation on a 980 Ventilator, Institution may not be able to place that 980 Ventilator promptly back into patient use.**

Warranty Disclaimer

The Software Package is intended to allow for remote adjustment of 980 Ventilators. It is entirely at Institution's discretion how to control, secure, and operate the 980 Ventilator and the Remote Access Feature to facilitate care to its patients. Institution is fully responsible for controlling security and access to the Software Package, and for using the Software Package to facilitate patient care. As with Institution's 980 Ventilators, Medtronic does not assume any responsibility for how the Institution provides, controls, or limits access to such 980 Ventilators for the provision of patient care at Institution's facility, or for any decision regarding the appropriateness of patient care.

Medtronic represents and warrants to Institution that the Omnitool, ESS, and Agent will perform substantially as described in the Documentation for ninety (90) days from the date such software was first made available to Institution. If Institution notifies Medtronic of defects during the warranty period, Medtronic will remove or replace the software. INSTITUTION'S SOLE AND EXCLUSIVE REMEDY FOR BREACH OF THIS LIMITED WARRANTY AND MEDTRONIC'S SOLE LIABILITY SHALL BE LIMITED TO REMOVAL OR REPLACEMENT AND SHALL NOT ENCOMPASS ANY OTHER DAMAGES.

Notwithstanding these warranty provisions, all of Medtronic's obligations with respect to such warranties shall be contingent on Institution's use of the software in accordance with these Terms and in accordance with the Documentation.

This warranty does not apply to and Medtronic shall have no warranty obligations with respect to any damages, malfunctions, or non-conformities caused to or by: (i) any failures of the software in the Software Package that are the result of accident, abuse, negligence, misapplication, extreme power surge or extreme electromagnetic field; or (ii) any software, hardware or other technology not provided by Medtronic.

Except as expressly provided above, Medtronic provides no other warranties with respect to the Software Package. Medtronic hereby disclaims all express, implied and statutory warranties with respect to the Software Package, including but not limited to the implied warranties of merchantability, fitness for a particular purpose and non-infringement.

Limitation of Liability

Medtronic does not assume any liability and has no responsibility for the payment of any damages, of any kind (including liability or damages arising out of or based on claims of product liability, negligence, failure to warn, warranty, use or inability to use, regardless of the legal theory on which any such damages or liability may be based and whether or not Medtronic has been advised of the possibility of any such damages or liability), for Institution's download of, installation of, use of, misuse of, or inability to use the Software Package or the Remote Access Feature, or for Institution's clinical practice, clinical strategies, and patient care. The use of the Software Package and the Remote Access Feature on any 980 Ventilator is at Institution's own volition and risk and is intended solely to assist with the public health and medical response to the COVID-19 pandemic, consistent with the FDA Guidance.

Compliance

Medtronic will collect and track financial and other information regarding transfers of value made by Medtronic to Institution in connection with providing the Software Package to Institution at no charge and report such information to state, federal, and/or other legal authorities as required in order for Medtronic to comply with any and all relevant state, federal, and/or other laws requiring such disclosure including, but not limited to, Section 2002 of the Affordable Care Act (the Federal Physician Payment Sunshine Act). Institution will provide Medtronic with all information reasonably requested by Medtronic in order for Medtronic to carry out the provisions of this paragraph. The information collected by Medtronic is subject to posting on a publicly available web site, as required by law.

Governing Law

This license is governed by the laws of the state of Minnesota, without regard to its conflict of law principles. Notwithstanding the foregoing, to the extent Institution is a federal agency (Veteran Administration Medical Center or the Defense Health Agency, etc.), the applicable law shall be governed in accordance with the Federal Acquisition Regulation. The United Nations Convention on Contracts for the International Sale of Goods does not apply to these Terms.